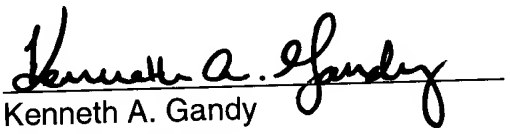
REMARKS

In response to the requirement set forth in the Office Action, applicant hereby requests that the CRF in the parent application, 09/441,315, be used to generate a CRF in the present application.

The applicant would also like to take this opportunity to inform the Examiner that the Reexamination Proceeding No. 90/006,098, concerning U.S. Patent No. 5,602,301, mentioned in applicant's prior Amendment dated March 3, 2003, has been concluded and has resulted in the issuance of a Reexamination Certificate. That Reexamination Certificate is attached hereto along with a supplemental IDS document in which it is identified. Please note that a Terminal Disclaimer has previously been filed in respect of U.S. Patent No. 5,602,301, in conjunction with the above-mentioned Amendment.

Favorable action and allowance of this application are requested. The Examiner is invited to contact the undersigned attorney by telephone if there any questions about this submission or other matters that may be handled in that fashion to expedite the allowance of this application.

Respectfully submitted,

By: 

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/878,011	06/08/2001	Loren J. Field	7037-440/IU-30-DIV-CON4	4537

7590 09/10/2003

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EXAMINER	
KETTER, JAMES S	

ART UNIT	PAPER NUMBER
1636	10

DATE MAILED: 09/10/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

DW

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.

EXAMINER	
ART UNIT	PAPER
	10

DATE MAILED:

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Commissioner for Patents

--See attached--

The reply filed on 24 June 2003 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): there is no actual language requesting that the CRF (Computer Readable Form) of the sequence listing be generated using the CRF of the parent application. Applicant has merely noted that the CRF of the parent file is the same as the paper copy of the sequence listing in the instant case. Applicant must submit a request that the CRF in the parent application be used to generate a CRF in the present application. See 37 CFR 1.111. Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE (1) MONTH or THIRTY (30) DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

Certain papers related to this application may be submitted directly to the Examiner by facsimile transmission at (703) 746-5155. The faxing of such papers must conform with the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993)(see 37 CFR ' 1.6(d)). To send the facsimile to the Art Unit instead, the Art Unit 1636 Fax number is (703) 305-7939. NOTE: If Applicant does submit a paper by fax to this number, the Examiner must be notified promptly, to ensure matching of the faxed paper to the application file, and the original signed copy should be retained by Applicant or Applicant's representative. (703) 308-4242 or (703) 305-3014 may be used without notification of the Examiner, with such faxed papers being handled in the manner of mailed responses. Applicant is encouraged to use the latter two fax numbers unless immediate action by the Examiner is

required, e.g., during discussions of claim language for allowable subject matter. NO DUPLICATE COPIES SHOULD BE SUBMITTED so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the Examiner with respect to the examination on the merits should be directed to James Ketter whose telephone number is (703) 308-1169. The Examiner normally can be reached on M-F (9:00-6:30), with alternate Fridays off.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Remy Yucel, can be reached at (703) 305-1998.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Jsk
August 25, 2003

JAMES KETTER
PRIMARY EXAMINER

US005602301C1

(12) REEXAMINATION CERTIFICATE (4832nd)

United States Patent
Field

(10) Number: US 5,602,301 C1
(45) Certificate Issued: Aug. 19, 2003

(54) NON-HUMAN MAMMAL HAVING A GRAFT AND METHODS OF DELIVERING PROTEIN TO MYOCARDIAL TISSUE

(75) Inventor: Loren J. Field, Indianapolis, IN (US)

(73) Assignee: Indiana University Foundation, Bloomington, IN (US)

Reexamination Request:
No. 90/006,098, Aug. 28, 2001

Reexamination Certificate for:
Patent No.: 5,602,301
Issued: Feb. 11, 1997
Appl. No.: 08/153,664
Filed: Nov. 16, 1993

Certificate of Correction issued Sep. 9, 1997.

Certificate of Correction issued Feb. 2, 1999.

(51) Int. Cl.[7] A01K 67/00; A01K 48/00; A01N 63/00; C12P 21/06; C12N 5/00

(52) U.S. Cl. 800/8; 424/93.21; 424/93.7; 435/69.1

(58) Field of Search 800/8; 424/93.1, 424/93.2, 93.21, 93.7

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Primary Examiner—Anne-Marie Falk

(57) ABSTRACT

Described are preferred myocardial grafts of skeletal myoblasts or cardiomyocytes, and cellular compositions and methods useful in obtaining the grafts. The myocardial grafts are stable and can be used, for example, to deliver recombinant proteins directly to the heart.

REEXAMINATION CERTIFICATE ISSUED UNDER 35 U.S.C. 307

THE PATENT IS HEREBY AMENDED AS INDICATED BELOW.

Matter enclosed in heavy brackets [ ] appeared in the patent, but has been deleted and is no longer a part of the patent; matter printed in italics indicates additions made to the patent.

AS A RESULT OF REEXAMINATION, IT HAS BEEN DETERMINED THAT:

Claims 5–7, 10 and 13 are cancelled.

Claims 1, 8, 9, 11 and 12 are determined to be patentable as amended.

Claims 2, 3 and 4, dependent on an amended claim, are determined to be patentable.

New claims 14–34 are added and determined to be patentable.

1. A non-human mammal which has a myocardial graft, the mammal comprising:

viable skeletal myoblasts or cardiomyoctes having a detectable marker directly introduced into the myocardial tissue of the mammal *such that the introduced skeletal myoblasts or cardiomyoctes form a stable myocardial graft in the mammal, said stable myocardial graft having cells viable for at least six months after said introducing.*

8. [The method of claim 5, wherein cardiomyocytes are directly introduced into the myocardial tissue] *A method for forming a stable myocardial graft in a mammal, the method comprising:*

directly introducing viable cardiomyocytes into the myocardial tissue of the mammal such that the introduced cardiomyocytes form a stable myocardial graft in the mammal.

9. The method of claim [5] *8*, wherein the myocardial graft is non-tumorigenic.

11. The method of claim [10] *27*, wherein the [stable graft is comprised of skeletal myoblasts] *skeletal myoblasts are genetically modified to express a DNA sequence encoding a protein, and wherein the DNA sequence is expressed sufficiently for delivery of the protein to the myocardial tissue.*

12. [The method of claim 10] *A method for delivering proteins to the myocardial tissue of a mammal, the method comprising:*

directly introducing viable cardiomyocytes expressing a DNA sequence encoding a protein into the myocardial tissue of the mammal such that the introduced cardiomyocytes form a stable graft, wherein the cardiomyocytes are genetically modified to express the DNA sequence, and wherein the DNA sequence is expressed sufficiently for delivery of the protein to the myocardial tissue, and further wherein the stable graft is comprised of cardiomyocytes.

14. The method of claim 8, wherein said myocardial graft has cells viable for at least six months after said introducing.

15. The method of claim 8, wherein said directly introducing comprises injecting.

16. The method of claim 14, wherein said directly introducing comprises injecting.

17. The method of claim 8, wherein said myocardial graft is directly juxtaposed to myocardial cells of the mammal.

18. The method of claim 8, wherein said myocardial tissue is in the left ventricular wall of the mammal.

19. A method for delivering proteins to the myocardial tissue of a mammal, the method comprising:

directly introducing viable skeletal myoblasts or cardiomyocytes expressing a DNA sequence encoding a protein into the myocardial tissue of the mammal such that the introduced skeletal myoblasts or cardiomyocytes form a stable graft, wherein the skeletal myoblasts or cardiomyocytes are genetically modified to express the DNA sequence, and wherein the DNA sequence is expressed sufficiently for delivery of the protein to the myocardial tissue, and further wherein said graft has cells viable for at least six months after said introducing.

20. The method of claim 19, wherein said directly introducing comprises injecting.

21. A method for delivering proteins to the myocardial tissue of a mammal, the method comprising:

directly introducing viable cardiomyocytes expressing a DNA sequence encoding a protein into the myocardial tissue of the mammal such that the introduced cardiomyocytes form a stable graft, wherein the DNA sequence is expressed sufficiently for delivery of the protein to the myocardial tissue.

22. The method of claim 21, wherein said directly introducing comprises injecting.

23. The method of claim 22, wherein said graft is directly juxtaposed to myocardial cells of the mammal.

24. A method for forming a stable myocardial graft in a mammal, the method comprising:

directly introducing viable skeletal myoblasts into the myocardial tissue of the mammal such that the introduced skeletal myoblasts form a stable myocardial graft in the mammal, said stable myocardial graft containing skeletal myocytes.

25. The method of claim 24, wherein the myocardial graft is non-tumorigenic.

26. The method of claim 24, wherein said directly introducing comprises injecting.

27. The method of claim 26, wherein said stable myocardial graft has cells viable for at least six months after said introducing.

28. The method of claim 24, wherein said graft is directly juxtaposed to myocardial cells of the mammal.

29. The method of claim 26, wherein said graft is directly juxtaposed to myocardial cells of the mammal.

30. A method for forming a stable myocardial graft in a mammal, the method comprising:

directly introducing viable skeletal myoblasts into the myocardial tissue of the mammal such that the introduced skeletal myoblasts form a stable myocardial graft in the mammal, said stable myocardial graft having cells viable for at least six months after said introducing.

31. The method of claim 30, wherein the myocardial graft is non-tumorigenic.

32. The method of claim 30, wherein said directly introducing comprises injecting.

33. The method of claim 30, wherein said graft is directly juxtaposed to myocardial cells of the mammal.

34. The method of claim 32, wherein said graft is directly juxtaposed to myocardial cells of the mammal.

* * * * *